Non-technical Abstract

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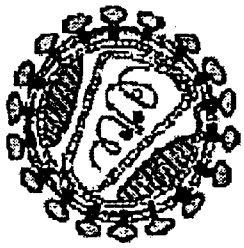

T-CELL INFUSION STUDY

"CD4 Zeta"

A new procedure has been found that takes some T-helper cells (CD4 cells) from the blood of an HIV-infected person, grows the cells in the laboratory and then gives these cells back using a needle put into a vein of the arm. So far, this has been shown to be safe and without many side-effects.

"CD4 Zeta" is a next step. CD4 Zeta is a "Gene Therapy" for HIV-infection. In this 5 month long study, some of your T-helper cells will be removed. Then, a small genetic code will be put into the removed T-cells. These cells will then be grown and increased in number in the laboratory, then given back to you. The small change in the gene of the T-cells lets them be tracked through the body; to include letting scientists know how long they live, where they go, and if they can reproduce. The genetic code placed into some of your T-cells is designed to seek out HIV-infected cells, attack and kill them. This study requires rectal biopsies where tiny snips of skin inside your rectum are removed to track the CD4 Zeta T-cells.

This study will also use Interleukin-2 (IL-2), which is a natural product found in the body that makes T-cells grow. In HIV, patients' IL-2 levels are often lowered. In this study, laboratory-made IL-2 will be given as a shot into the fat under your skin.

There are 3 arms in this study:

Group 1:	(8 people) will get IL-2 shots
Group 2:	(8 people) will get one dose of CD4-Zeta-gene-changed T-helper cells
Group 3:	(8 people) will get IL-2 shots and one dose of CD4-Zeta-gene-changed T-helper cells

A computer will assign you to one of these groups. Everyone in the CD4 Zeta Study will know what research treatment they are getting.

STUDY FACTS

PURPOSE. *Using CD4-Zeta-gene-changed T-helper cells, find out how long they live, where they travel in the body, and whether they decrease the amount of HIV in 24 HIV-infected persons.*

INCLUSION CRITERIA.

- *Live locally;*
- *DoD Healthcare Beneficiary;*
- *18 years or older;*
- *HIV-positive;*
- *Successful antiretroviral treatment of 2 or more drugs for at least 8 weeks before the study; and willing to stay on this during the whole study;*
- *Undetectable viral load for at least 8 weeks before the study;*
- *Average T-helper cells $\geq$ 200 mm^3*
- *Able to give informed consent*
- *See protocol coordinator for more details and other requirements*

POTENTIAL BENEFITS.

- *Increased T-helper cell count*
- *Find out if CD4 Zeta is additive to anti-HIV drug treatment;*
- *Possible improvement of how well your T-cells work*

PRINCIPAL INVESTIGATOR NAME AND ADDRESS.

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STUDY LOCATION.

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